

HUMAN SERVICES DEPARTMENT[441]

Adopted and Filed

Rule making related to prescription drug automatic refill program

The Human Services Department hereby amends Chapter 78, “Amount, Duration and Scope of Medical and Remedial Services,” Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is adopted under the authority provided in Iowa Code section 249A.4.

State or Federal Law Implemented

This rule making implements, in whole or in part, Iowa Code section 249A.4.

Purpose and Summary

This rule making establishes pharmacy policies and procedures for Medicaid coverage and reimbursement of prescription drug refills through an automatic refill program, rather than prohibiting such a program. This may improve medication adherence for chronic medical conditions. Some pharmacies may currently offer this type of program, and Medicaid proposes to standardize the requirements to ensure medical necessity and prevent waste. The United States Government Accountability Office (GAO) recommended in its July 2015 report, “Medicaid: Additional Reporting May Help CMS Oversee Prescription-Drug Fraud Controls,” that Medicaid programs review pharmacy automatic refill programs and corresponding Medicaid policies as a potential concern for waste and unnecessary costs.

Public Comment and Changes to Rule Making

Notice of Intended Action for this rule making was published in the Iowa Administrative Bulletin on October 21, 2020, as **ARC 5228C**. The Department received three comments from two respondents on the proposed amendment. The comments and corresponding responses from the Department are divided into three topic areas as follows:

A. Automatic prescription refill allowance. There were two comments in this topic area.

1. One respondent who operates retail drug stores, telepharmacies, and closed-door pharmacies expressed support for the Department’s efforts to expand the use of automatic refill programs to Medicaid patients. The respondent is strongly in favor of the amendment to subparagraph 78.2(6)“b”(2), allowing Medicaid patients to participate in automatic refill programs.

2. One respondent expressed support for policies to help reduce waste, stockpiling, and potential abuse, indicating this could be minimized if patients received automatic refills from a physical location. The respondent stated that the touchpoint with the patient is an opportunity to promote proper adherence and medication use, and the risk of stockpiling or waste is greatly reduced.

Department response: The Department supports appropriate implementation of an automatic refill program by a pharmacy to improve medication compliance while controlling for waste and abuse. The allowance for this program is not limited to a physical location pharmacy. However, the oversight by the pharmacy for this program is the same for either a mail order or physical location pharmacy in regard to all consent documentations, including verification of continued medical necessity prior to dispensing, delivering or mailing to the member.

B. Medication synchronization. There was one comment in this topic area.

The respondent commented on the use of a medication synchronization program as part of the respondent’s automatic refill program and indicated allowing Medicaid patients to enroll in medication synchronization programs improves medication compliance.

Department response: Medication synchronization services are not a currently covered policy under Iowa Medicaid, and this rule language related to automatic refill programs will not change that. The refill tolerance will be required to be met even with the allowance of an automatic refill program.

C. Documentation requirements. There was one comment in this topic area.

The respondent requested clarification on what would satisfy the requirements for documentation of consent to opt in or continue automatic refills. Examples noted how pharmacies currently capture similar requirements were signature capture, written record, or a checkbox on the pharmacy software for verbal authorization with a time/date stamp. The respondent requested broad enforcement of this requirement to ensure pharmacies have flexibility in documenting patient consent.

Department response: The Department updated the rule language to clarify that consent for automated refills should be in electronic or written form. The consent process must support all requirements as noted in the rules, including but not limited to the name of the member or representative consenting and the date of consent, as well as a record of selected prescriptions for automatic refill.

A change from the Notice was made to the last bulleted paragraph of 78.2(6)“b”(2)“2” to clarify how consent would be obtained.

Adoption of Rule Making

This rule making was adopted by the Council on Human Services on December 10, 2020.

Fiscal Impact

This rule making has no fiscal impact to the State of Iowa.

Jobs Impact

After analysis and review of this rule making, no impact on jobs has been found.

Waivers

Any person who believes that the application of the discretionary provisions of this rule making would result in hardship or injustice to that person may petition the Department for a waiver of the discretionary provisions, if any, pursuant to rule 441—1.8(17A,217).

Review by Administrative Rules Review Committee

The Administrative Rules Review Committee, a bipartisan legislative committee which oversees rule making by executive branch agencies, may, on its own motion or on written request by any individual or group, review this rule making at its [regular monthly meeting](#) or at a special meeting. The Committee’s meetings are open to the public, and interested persons may be heard as provided in Iowa Code section 17A.8(6).

Effective Date

This rule making will become effective on March 1, 2021.

The following rule-making action is adopted:

Amend subparagraph **78.2(6)“b”(2)** as follows:

(2) Automatic refills.

~~1. Automatic refills are not allowed. A request specific to each medication is required.~~

~~2. All prescription refills shall be initiated by a request at the time of each fill by the prescriber, Medicaid member or person acting as an agent of the member, based on continued medical necessity.~~

1. Automatic refills are allowed. Participation in an automatic refill program is voluntary and opt-in only, on a drug-by-drug basis.

2. The program must have:

- Easy-to-locate contact information through telephone, the program’s website, or both;

- Easy-to-understand patient materials on how to select or unselect drug(s) for inclusion and how to disenroll;
- Confirmation that the member wants to continue in the automatic refill program at least annually;
- Confirmation of continued medical necessity provided by the Medicaid member or person acting as an authorized representative of the member, before the member receives the medication at the pharmacy or before the medication is mailed or delivered to the member, without which confirmation the drug(s) must be credited back to the Medicaid program; and
- Records of all consents, which must be in electronic or written format and must be available for review by auditors.

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EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 12/30/20.